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October 7, 2019

Via ECF

The Honorable Colleen McMahon
United States District Court
Southern District of New York
500 Pearl Street, Room 2550
New York, New York 10007

RE: *In re Namenda Direct Purchaser Antitrust Litig.*, No. 15-cv-07488-CM-RWL

Dear Judge McMahon:

Appended hereto as Exhibit A, please find Plaintiffs' proposed statement regarding Forest's unlawful "hard switch," to be read to the jury at the start of Phase 2 of the trial in the above matter. The statement reflects the three subjects to which the Court has determined collateral estoppel applies. Plaintiffs drew the proposed statements of predicate fact directly from the Court's decision on collateral estoppel, Judge Sweet's December 11, 2014 Opinion, and the Second Circuit's affirmance of that Opinion. Plaintiffs believe that the predicate facts and holding regarding Forest's monopoly power are also applicable to Phase 1.

Respectfully submitted,

/s/ Bruce E. Gerstein
Bruce E. Gerstein

EXHIBIT A

PLAINTIFFS' PROPOSED SUMMARY OF PRIOR FINDINGS REGARDING FOREST'S ILLEGAL HARD SWITCH PRODUCT HOP

Plaintiffs also allege they were overcharged as a result of conduct by Forest known as a "hard switch product hop," also referred to as a "hard switch." You heard previously that Forest launched immediate-release Namenda tablets in the United States in January 2004 (which you have heard called Namenda IR tablets throughout this trial), and launched extended-release Namenda XR capsules on June 13, 2013.[1] Namenda IR tablets were facing generic competition no later than July 2015, and generic Namenda IR tablets were expected to quickly take most of the sales of branded Namenda IR tablets.[2] There are state generic drug substitution laws that facilitate this generic substitution. "[A]ll 50 states and the District of Columbia have drug substitution laws" that "either permit or require pharmacists to dispense a therapeutically equivalent, lower-cost generic drug in place of a brand drug absent express direction from the prescribing physician that the prescription must be dispensed as written."[3] Namenda IR and XR contain the same active ingredient, memantine hydrochloride, but because Namenda IR is an immediate-release tablet, and Namenda XR is an extended release capsule, they are not considered "therapeutic equivalents" under FDA regulations, even though they have the same therapeutic effect.[4] As a result, a pharmacist presented with a prescription for Namenda XR cannot fill that prescription with a less-expensive generic version of Namenda IR through the automatic substitution process.[5]

The "hard switch" refers to Forest's conduct announcing its intention to withdraw immediate release Namenda tablets from the market. "[O]n February 14, 2014, Forest announced (via a press release, notice to the FDA, and letters to physicians and patients) that it would discontinue sales of Namenda IR on August 15, 2014," before generic versions of Namenda IR tablets

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[1] Revised Pretrial Order, May 1, 2019, ECF No. 699 at 3 (Stipulated Facts, Nos. 10, 13).

[2] *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 647 (2d Cir. 2015) ("*Namenda II*") ("A brand drug's exclusivity period is significant because when that period ends and generic versions enter the market, the brand drug often loses more than 80 to 90% of the market within six months. This period following the end of patent exclusivity has been referred to in this litigation and throughout the industry as the 'patent cliff.'"); *In re Namenda Direct Purchaser Antitrust Litig.*, No. 15 Civ. 7488 (CM), 2017 WL 4358244, at *6 (S.D.N.Y. May 23, 2017)(McMahon, J.)(under various settlements Forest had reached with generic competitors, "the Generic Competitors could not begin selling their drugs until July 11, 2015.").

[3] *Namenda II*, 787 F.3d at 644-45 (footnotes omitted).

[4] *Namenda II*, 787 F.3d at 647 ("Namenda IR and Namenda XR have the same active ingredient and the same therapeutic effect."); *id*. ("Because Namenda XR has a different strength and daily dosage regimen—Namenda IR involves two immediate-release tablets of 10mg each and Namenda XR involves one 28 mg extended-release capsule—the generic IR versions that are poised to enter the market will be therapeutically equivalent under FDA regulations to Namenda IR but not to Namenda XR. Therefore, pharmacists are prohibited from substituting generic IR for Namenda XR under most, if not all, state drug substitution laws.")(footnote omitted)).

[5] *Namenda II*, 787 F.3d at 647.

became available, leaving Namenda XR capsules as the only memantine drug available.[6] Another court has already found that Defendants' hard switch violated federal antitrust law, specifically Section 2 of the Sherman Act which prohibits unlawful monopolization. Therefore, I instruct you that, for purposes of this trial and your deliberations at the conclusion of this case, the following facts are binding on you, and you must accept as true the following facts:

1. Defendants had monopoly power over the United States memantine market.[7] Before generic versions of Namenda IR became available in July 2015, brand name Namenda IR and XR were the only memantine therapies available to Alzheimer's patients, and there are no reasonably interchangeable substitutes for memantine.[8]

2. "Forest's actions, starting with the February 2014 announcement of the upcoming withdrawal of Namenda IR from the market, were both coercive and anticompetitive."[9]

3. "'[A]nnouncing the imminent discontinuation of a drug is tantamount withdrawal,'" meaning it is the same as withdrawing the drug from the market.[10]

4. "Forest's February 2014 announcement was multi-faceted. In addition to issuing a press release about the upcoming discontinuance of Namenda IR sales, Forest 'published open letters to physicians and caregivers on its website announcing its plans to discontinue Namenda IR and urging caregivers to speak with their loved ones' "healthcare provider[s] as soon as possible to discuss switching to Namenda XR."""[11]

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[6] *In re Namenda Direct Purchaser Antitrust Litig.*, 2017 WL 4358244, at *7.

[7] *In re Namenda Direct Purchaser Antitrust Litig.*, 2017 WL 4358244, at *16 ("Forest is precluded from relitigating. . . (1) whether it possessed monopoly power over the U.S. memantine market up until the entry of generic competition").

[8] *New York v. Actavis, PLC*, No. 14 Civ. 7473, 2014 WL 7015198, at *35 (S.D.N.Y. Dec. 11, 2014) (Sweet, J.) ("*Namenda I*")("A single product may constitute a relevant market where there are no reasonably interchangeable substitutes."); *id*. ("The appropriate geographic and product market for antitrust purposes in this case has been established as the memantine market in the United States."); *Namenda II*, 787 F.3d at 652 ("the parties do not dispute that Defendants possess monopoly power").

[9] *In re Namenda Direct Purchaser Antitrust Litig.*, 2017 WL 4358244, at *11. *Id.* at *16 ("Forest is precluded from relitigating. . .(2) whether its February 2014 announcement of the upcoming discontinuation of Namenda IR was coercive and anticompetitive").

[10] *In re Namenda Direct Purchaser Antitrust Litig.*, 2017 WL 4358244, at *11 (quoting *Namenda II*, 787 F. 3d at 648).

[11] *In re Namenda Direct Purchaser Antitrust Litig.*, 2017 WL 4358244, at *11 (quoting *Namenda I*, 2014 WL 7015198, at *18).

5. "'Physicians interpreted the announcement as a warning to switch their patients from Namenda IR to Namenda XR.'"[12]

6. Forest also "sent a letter to the Centers for Medicare & Medicaid Services to remove Namenda IR from its Formulary Reference File—an unusual step that would make it more likely that health insurance plans would not cover Namenda IR starting in January 2015."[13]

7. "Forest's hard switch 'crosse[d] the line from persuasion to coercion,'" because Forest had monopoly power and there were no reasonable substitutes for Namenda IR, and therefore "'[b]y effectively withdrawing Namenda IR prior to generic entry, [Forest] *forced* patients to switch from Namenda IR to XR—the only other memantine drug on the market.'"[14]

8. The hard switch was anticompetitive — meaning it harmed generic competition — because once patients and physicians switched from Namenda IR to Namenda XR, they "would be very unlikely to switch back to twice-daily [Namenda] IR therapy even after less-expensive generic IR bec[ame] available, due to the high transaction costs associated with Alzheimer's patients first switching from" Namenda IR to Namenda XR and then back to IR.[15] Switching from Namenda XR back to generic Namenda IR is called "reverse commuting" but there was a "relatively low risk [to Forest] that patients would reverse commute to generic versions of Namenda IR, because Alzheimer's patients are 'especially vulnerable' and physicians are therefore reluctant to change their medications, even if it results in cost savings."[16]

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[12] *In re Namenda Direct Purchaser Antitrust Litig.*, 2017 WL 4358244, at *11 (quoting *Namenda I*, 2014 WL 7015198 at *18).

[13] *In re Namenda Direct Purchaser Antitrust Litig.*, 2017 WL 4358244, at *11 (citing *Namenda I*, 2014 WL 7015198 at *18).

[14] *In re Namenda Direct Purchaser Antitrust Litig.*, 2017 WL 4358244, at *11 (emphasis in original) (quoting *Namenda II*, 787 F.3d at 654). *See also Namenda II*, 787 F.3d at 649 ("Withdrawing Namenda IR from the market prior to generic entry forces Alzheimer's patients dependent on memantine therapy to switch to Namenda XR because it is the only available alternative.").

[15] *Namenda II*, 787 F.3d at 649.

[16] *In re Namenda Direct Purchaser Antitrust Litig.*, 2017 WL 4358244, at *8 (citing *Namenda I*, 2014 WL 7015198, at *28-31).

9. Generic Namenda IR could not be automatically substituted for Namenda XR by pharmacies, and such automatic substitution is the "'*only* cost-efficient means of competing available to generic manufacturers.'"[17]

10. By lowering the number of Namenda IR prescriptions, Forest's hard switch would lower sales of less expensive generic versions of Namenda IR.[18]

11. "Importantly, [a prior court] found that [as of December 2014] Forest's hard-switch tactics had *already* resulted in more customers converting from Namenda IR to Namenda XR than Forest had estimated would convert voluntarily."[19] As of December 2014, more "'existing patients [had] converted from Namenda IR to Namenda XR in anticipation of the lack of availability of Namenda IR'. . . than the 30% that Forest had estimated would convert if only soft-switch tactics were employed."[20]

12. In a "soft-switch," "a manufacturer may aggressively promote and market the follow-on drug [here, Namenda XR] to patients and doctors, or may reduce its price compared to the original drug, in order to incentive voluntary conversions."[21] "[A]fter various soft-switch tactics failed, Forest decided to pursue a hard switch in order to preserve its market share."[22]

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[17] *In re Namenda Direct Purchaser Antitrust Litig.*, 2017 WL 4358244, at *11 (emphasis in original)(quoting *Namenda II*, 787 F.3d at 655-56).

[18] *In re Namenda Direct Purchaser Antitrust Litig.*, 2017 WL 4358244, at *11 ("Both Judge Sweet and the Second Circuit determined that the hard switch also impeded competition."); ("Because most generic substitution laws (including New York's) would prevent a pharmacist from automatically substituting a prescription for Namenda XR with a generic version of Namenda IR (without first consulting the patient's physician), Judge Sweet concluded that 'generics are unlikely to be able to make substantial sales.'") (quoting *Namenda I*, 2014 WL 7015198, at *26).

[19] *In re Namenda Direct Purchaser Antitrust Litig.*, 2017 WL 4358244, at *12 (emphasis in original).

[20] *In re Namenda Direct Purchaser Antitrust Litig.*, 2017 WL 4358244, at *12 (quoting *Namenda I*, 2014 WL 7015198 at *29) (alteration in original); (unredacted version of *Namenda I*, filed at ECF No. 666-18 at 80-81).

[21] *In re Namenda Direct Purchaser Antitrust Litig.*, 2017 WL 4358244, at *5. *See also Namenda II*, 787 F.3d at 648 (describing soft switch).

[22] *In re Namenda Direct Purchaser Antitrust Litig.*, 2017 WL 4358244, at *8 (citing *Namenda I*, 2014 WL 7015198 at *16-22).

13. Forest had no legal justification for its illegal conduct.[23] One of Forest's own corporate officers, CEO Brenton Saunders, stated that the "purpose of the hard switch was to impede generic competition."[24]

All of these facts were decided by a court in a prior lawsuit brought by the New York State Attorney General and Forest is not permitted to dispute them again.

As to Plaintiffs' claims regarding the hard switch product hop, you need decide only if Plaintiffs paid some overcharge that was materially caused by the hard switch product hop, and if so, how much the overcharges were. Because the hard switch was illegal, a prior court in December 2014 issued an order called a preliminary injunction that ordered Forest to keep Namenda IR on the market until August 2015. Forest did so. The parties here dispute whether that injunction cured the anticompetitive effects of Forest's illegal conduct.

You also will be asked to decide the overcharge damages suffered by the Class as a result of the illegal reverse payment and delay in generic competition that you have already found, and damages from the reverse payment and the hard switch product hop combined. At the conclusion of the case I will give you further instructions about these issues.

[23] *In re Namenda Direct Purchaser Antitrust Litig.*, 2017 WL 4358244, at *16 ("Forest is precluded from relitigating. . . (3) whether Forest had any non-pretextual procompetitive justification for its illegal conduct.").

[24] *In re Namenda Direct Purchaser Antitrust Litig.*, 2017 WL 4358244, at *12 ("Both Judge Sweet and the Second Circuit determined that 'All of [Forest's] procompetitive justifications for withdrawing [Namenda] IR are pretextual.' *Namenda II*, 787 F.3d at 658. This conclusion was based, in part, on statements made by one of Forest's own corporate officers, Brenton Saunders, who stated on an earning call that the purpose of the hard switch was to impede generic competition. *Namenda I*, 2014 WL 7015198, at *40."). *See also Namenda II*, 787 F.3d at 658 ("All of Defendants' procompetitive justifications for withdrawing IR are pretextual. The record is replete with evidence showing that Defendants were, in the words of Defendants' own CEO, 'trying to ...put up barriers or obstacles' to generic competition.") (ellipsis in original).